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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,986	02/05/2004	Jenny Louie-Helm	3100-0003.10	7141

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,986	LOUIE-HELM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 02/05/04.

Priority

1. Examiner acknowledges this application as a division of Application No. 10/014,750, filed October 25, 2001. However, applicants have not set forth the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 10, 11, 17 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. (US 5,830,576).

Mehra discloses a diuretic formulation that comprises sodium carboxymethyl cellulose or hydroxypropylmethyl cellulose or methylcellulose or alginate or carrageenan (column 3, lines 38-42, Example 19) and Mehra uses the USP disintegration test to determine the disintegration of the formed granules (column 8, lines 13-20). Methylcellulose is listed in instant claim 6 as a hydrophilic polymer. In general, the release profile of dosage forms is a predetermined condition when dosage forms are formulated as is evident in the matrix polymers used with the active agent that would make a dosage form controlled release or immediate release; and in

general in vitro test analysis correlate in vivo pattern of drug release. The method of claim 17 is a method of administering and the dosage form of Mehra is administered.

4. Claims 1-8, 10-13, 17, 18 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Franz et al. (US 5,232,704).

Franz discloses using in vitro release study in anticipation that the release profile of prepared dosage formulation would be sustained according to the in vitro release study data (column 9, lines 7-30; column 12, lines 25-50; abstract); the formulation comprises active ingredient such as prostaglandin and non-steroidal anti-inflammatory drug (column 3, lines 15-33; column 4, lines 4-10), hydroxypropyl methylcellulose, carboxymethylcellulose and PVP or polyethylene glycol (column 5, lines 15-33). Frantz administers the formulation to subject in the fed state and once daily (column 14, 36-44).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (US 5,972,389 cited by applicants in the specification) in view of applicants' admitted prior art.

Shell discloses controlled release tablet or capsule containing particles of sparingly soluble drugs, insoluble drugs or soluble drugs dispersed in swellable/erodible polymer such as polyethylene oxide and hydroxypropyl methylcellulose (abstract; Figs. 1-3;column 3, lines 21-59); the drugs delivered to the GI in fed mode are ciprofloxacin and calcium carbonate (column

4, line 65; column 5, lines 10-13); ACE inhibitors can be combined with diuretic (column 10, lines 14-24). While Shell indicates that the controlled release dosage form swells, erodes and disintegrates upon contact with gastric fluid (column 2, lines 1-14), Shell does not disclose testing disintegration of the dosage form in vitro. However, applicants admit (paragraph [0005] of the instant specification) that disintegration test is used to supplement dissolution data to predict in vivo drug release profile. There is no demonstration by applicants that using disintegration test provides unusual results over dissolution test. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare sustained/controlled release dosage forms according to Shell and having a knowledge of the in vitro dissolution of the drugs of interest with the expectation that the dosage forms upon administration would release active agents in accordance with anticipated controlled/sustained delivery profile. "A far more predictive test for drug release in vivo" is relative and does not constitute a showing. In the absence of a showing, using in vitro disintegration test data to correlate in vivo drug release is not inventive over using in vitro dissolution test data to predict the in vivo drug release.

Other matters:

Claims 1-26 are examined. However, claim 17 is a method of delivering pharmacologically active agent to the upper GI, while claim 1 is a method of selecting an optimized controlled release dosage form. Claim 17 and claim 1 are capable of supporting different patents within the art. It is respectfully requested of applicants to comment/discuss or provide any reasons why invention 1, represented by claim 1 and invention II represented by claim 17 may be equivalent and as such may not be restricted.

Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 1-3 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 49-51 of copending Application No. 10/281,284. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

9. Claims 1-3 and 25 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 47-49 of copending Application No. 10/293,217. Instant claims 1 and 25 are the same as claim 47 of copending application 10/293,217. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Curatolo et al. (US 6,068,859) discloses a controlled release dosage form in tablet, capsule, multiparticulate or sachet form (column 2, lines 13-31; column 3, lines 50-67; column 7, lines 37-47; column 8, lines 3-55; columns 11-17) and Curatolo cites Yoshitomi et al. in regards to "Evaluation of Enteric Coated Tablet Sensitive to Pancreatic Lipase I. In vitro Disintegration Test."

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600